

(IL-1b, IL-6, IL-8, IFN- γ , MIF and TNF- α). We have observed clinical differences in the rates of mixed chimerism and GVHD depending on when the alemtuzumab is given. This data suggests that the cytokine milieu may contribute to the development of GVHD and Transplant Related Morbidity (TRM).

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OUTCOMES OF ALLOGENEIC HEMATOPOIETIC STEM CELL TRANSPLANTATION IN COMMUNITY CANCER CENTERS: SINGLE INSTITUTION EXPERIENCE

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Variability in outcomes after hematopoietic stem cell transplantation (HCT) due to differences in health care delivery is traditionally referred to as "center effect". Data analysis by CIBMTR demonstrated improved day 100 survival after related donor (RD) HCT with greater physician involvement in patient's care regardless of medical school affiliation. We hypothesized that the greater physician involvement in patient's care at our community transplant center would compensate for the lack of infrastructure available to academic centers and result in comparable outcomes. We retrospectively reviewed the medical records of 50 consecutive patients who underwent matched unrelated (MUD) HCT (n = 26) or RD HCT (n = 24) for hematological malignancies between August 2007 and

April 2010. GVHD prophylaxis used was Tacrolimus/Methotrexate or Tacrolimus/Mycophenolate. MUD HCT recipients received ATG in addition. Twenty one (42%) and twenty eight patients (56%) of cohort had progressive/persistent disease and high risk cytogenetics at time of transplant respectively. Thirty three patients (66%) had Charlson Co-morbidity index of 3 or more. Patients characteristic is shown in the table below.

OS at 100 days and 1 year were 86% and 67% respectively. There was no statistical difference in OS between RD and MUD; (83% vs. 88% at day 100 and 74% vs. 64% at 1 year for RD and MUD recipients respectively, $P = 0.85$). DFS was 55% at 1 year. Again, there was no statistical significance difference in DFS between RD and MUD at 1 year ($P = 0.48$). The cumulative incidence of relapse was 16% at 1 year (21% for RD and 12% for MUD). We found no difference in the cumulative incidence of NRM between RD and MUD recipients at day 100 (12%). In contrast, NRM was higher at 1 year in MUD recipients of 34% vs. 25% for the RD recipients. The overall cumulative incidence of acute GVHD grade II-IV was 47.8% with incidence of severe GVHD grade III/IV of 16%. The cumulative incidence of chronic GVHD was 67.6%.

Conclusions: Allogeneic HCT outcomes in the community seem to be comparable to outcomes reported in literature. In this single institution experience, despite the absence of direct cause and effect relationship, the greater involvement of physicians in the patient's care may have contributed to the improved outcomes in this high risk cohort of patients. Community transplant centers may contribute in the future to meet the increased demands for allogeneic HCT with reasonable outcomes.

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PRELIMINARY RESULTS OF PHASE II TRIAL OF CLOFARABINE WITH PARENTERAL BUSULFAN (CLO/BU) FOLLOWED BY ALLOGENEIC RELATED OR UNRELATED DONOR TRANSPLANTATION FOR THE TREATMENT OF HEMATOLOGIC MALIGNANCIES

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BACKGROUND: RIT regimens are common, but relapse remains a problem. We proposed and tested a mid-intensity regimen using clofarabine (CLO) with busulfan (BU). We hypothesized this combo would be well tolerated and offer greater anti-leukemic efficacy than existing RIT regimens.

METHODS: We enrolled 20 patients on this single IST, with AML (10), ALL (1), CLL (1), MDS (2) and MDS-AML (6). 15 patients had prior therapies. The regimen was: CLO 40mg/m² iv daily x5, BU 3.2 mg/kg iv daily x2, followed by 1 rest day, followed by HSCT. Donors were matched at A, B, C, DR, DQ using DNA SBT or mid-res DNA typing. Mismatch ≤ 1 antigen was allowed. GVHD prophylaxis was FK506 and MTX 5mg/m² iv (d 1,3,6).

RESULTS: Endpoints included toxicity, engraftment, incidence/severity of AGVHD, and disease response.

All patients experienced grade 4 hem tox. Median time to ANC recovery (18/20 patients used GCSF) was 13 days (d9 - d17). Engraftment ($> 80\%$ donor chim. at d30) occurred in all patients by FISH and/or STR. Selected tox. included; 2 patients - hand/foot syndrome (1 Gr. 3, REL.); 1 resp. failure (Gr. 3 poss. REL) resolved completely; 5 patients - elevated ALT/AST (Gr.3-4, REL) resolving at regimen completion; other tox. were \leq Gr. 2. TRM was non-existent in this study.

18 patients developed AGVHD by d100 - 83% grade 1-2; 17% grade 3-4. No deaths attributed to AGVHD following study regimen.

Disease responses are: 11 (58%) patients, in relapse/active disease prior to CLO/BU, achieved CR by d30. 7 (37%) patients in CR at study entry, remained so at d30. 1 patient was N/E for disease response at d30. 1 patient (w / CLL) achieved CR at d132. 7 (37%) patients relapsed (M. d120 (d60 - d699)). 12 (60%) patients expired (M. d222 (d92 - d438)): cardiac arrest (1, d316); asp. pneumonia (1, d158); TTP (1, d438); AGVHD - post DLI (1, d175); relapse (4, M. d192 (d150 - d415)); persistent disease (1, d161); MSOF (1, d92); ITP (1, d307); Pulmonary Embolus (1, d233). Of 19 evaluable patients, 6 (32%) remain in remission with a median follow up of 946 days (31 months) (d396 - d1236).

Table 1. Patients characteristic

Number of patients	50 (100%)
Age	Median 56 (Range 23-71)
Patients above the age of 55	27 (54%)
Patients below the age of 55	23 (46%)
Match related (RD)	23 (46%)
Mismatched related 5/6	1 (2%)
Matched unrelated (MUD)	22 (44%)
Mismatched unrelated	4 (8%)
Male	30 (60%)
Female	20 (40%)
Diagnosis	
AML/MDS	26 (52%)
ALL	8 (16%)
Myelofibrosis	2 (4%)
CLL	2 (4%)
T-cell prolymphocytic leukemia	2 (4%)
CML (accelerated phase)	1 (2%)
HD	2 (4%)
Severe aplastic anemia	1 (2%)
Non Hodgkins lymphoma	3 (6%)
Multiple myeloma	3 (6%)
Stem cell source	Peripheral stem cells 50 (100%)
Status at transplant	
Complete remission - I	20 (40%)
Complete remission-2	9 (18%)
Progressive disease	7 (14%)
Persistent disease	14 (28%)
Prior Transplants	
Autologous	7; non tandem (14%)
Allogeneic related	5 (10%)
Cytogenetics	
High Risk	28 (56%)
Normal	19 (38%)
Not available	3 (6%)
Charlson Comorbidity Index	
Score 0	7 (14%)
Score 1-2	10 (20%)
Score 3-4	20 (40%)
Score 5 and above	13 (26%)
Conditioning Regimens	
Full Intensity (FIC)	20 (40%)
Reduced Intensity(RIC)	21 (42%)
Non Myeloablative (NMA)	9 (18%)

GVHD, graft versus host disease; OS, overall survival; DFS, disease free survival; NRM, non relapse mortality; NMA, Flu/TBI, RIC, FluBU-2/Flu-Mel, FIC FluBU-4/BUCY/CYTBI